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10/516,864	03/30/2006	Wen-Luan Wendy Hsiao	32144183.4	8549

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WILKINSON & GRIST
6TH FLOOR, PRINCE'S BUILDING
CHATER ROAD, CENTRAL
HONG KONG,
CHINA

EXAMINER	
GOLDBERG, JEANINE ANNE	
ART UNIT	PAPER NUMBER
1634	

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Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

Office Action Summary	Application No.	Applicant(s)	
	10/516,864	HSIAO ET AL.	
	Examiner	Art Unit	
	JEANINE A. GOLDBERG	1634	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on *25 May 2009*.

2a)☒ This action is **FINAL**. 2b)☐ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *1-5 and 30-37* is/are pending in the application.

4a) Of the above claim(s) _____ is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) *1-5, 30-37* is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on _____ is/are: a)☐ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

12)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

1) ☐ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☐ Information Disclosure Statement(s) (PTO/SB/08) Paper No(s)/Mail Date _____.
4) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____.
5) ☐ Notice of Informal Patent Application
6) ☐ Other: _____.

DETAILED ACTION

1. This action is in response to the papers filed May 25, 2009. Currently, claims 1-5, 30-37 are pending.

2. All arguments have been thoroughly reviewed but are deemed non-persuasive for the reasons which follow.

3. Any objections and rejections not reiterated below are hereby withdrawn.

4. This action is FINAL.

Election/Restrictions

5. Applicant's election with traverse of Group 1, Claims 1-29 directed to gene-encoded beta-catenin in the paper filed August 6, 2007 is acknowledged.

The response asserts that the practice regarding nucleotide sequences permits examination of up to ten sequences as set forth in the 1996 OG notice.

An OG Notice published March 27, 2007 rescinded the 1996 OG Notice that provided for a partial waiver of the requirements for restriction practice by permitting examination of a reasonable number, up to ten, independent and distinct polynucleotide molecules in a single 35 USC 111(a) or 35 USC 371 application. The Notice indicated that the standard of independence and distinctness would be applied to polynucleotide claims filed in an application under 35 USC 111(a). Additionally, the March 27, 2007 OG Notice specifically spoke to the issue of burden of searching more than one independent and distinct invention.

Applicant was provided an opportunity to specifically state on the record that the species were not patentably distinct. "Should applicant traverse on the ground that the inventions or species are not patentably distinct, applicant should submit evidence or identify such evidence now of record showing the inventions or species to be obvious variants or clearly admit on the record that this is the case. In either instance, if the examiner finds one of the inventions unpatentable over the prior art, the evidence or admission may be used in a rejection under 35 U.S.C.103(a) of the other invention." Applicants do not appear to have availed them of this opportunity.

The response asserts that election of species practice requires that the examiner must examine all members of the Markush group if the search may be made without serious burden. The response asserts that examination of a gene-encoded beta catenin; a gene-encoded alpha-catenin; and a gene encoded E-cadherin would not place undue burden upon the examiner. This argument has been reviewed but is not considered persuasive because each of these genes encode distinct proteins. Although the applicant asserts that the genes are associated, the genes would require a separate search and examination.

The requirement is still deemed proper and is therefore made FINAL.

Priority

6. This application is a 371 of PCT/US03/20587, filed June 27, 2003 and provisional application 60/392,191, filed June 28, 2002.

Drawings

7. The correction to the drawings has been reviewed. Drawing pages 4-5 have been cancelled as requested by applicant.

Information Disclosure Statement

8. The listing of references in the specification is not a proper information disclosure statement. 37 CFR 1.98(b) requires a list of all patents, publications, or other information submitted for consideration by the Office, and MPEP § 609 A(1) states, "the list may not be incorporated into the specification but must be submitted in a separate paper." Therefore, unless the references have been cited by the examiner on form PTO-892, they have not been considered.

Pages 16-17 contains a list of references. Any referecnes appear in the list and not listed on the IDS have not been considered.

Claim Rejections - 35 USC § 112- Enablement

The following is a quotation of the first paragraph of 35 U.S.C. 112:

> The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same and shall set forth the best mode contemplated by the inventor of carrying out his invention.

9. Claims 1-5, 30-37 are rejected under 35 U.S.C. 112, first paragraph, as containing subject matter which was not described in the specification in such a way as to enable one skilled in the art to which it pertains, or with which it is most nearly connected, to make and/or use the invention.

Factors to be considered in determining whether a disclosure meets the enablement requirement of 35 USC 112, first paragraph, have been described by the court in *In re Wands*, 8 USPQ2d 1400 (CA FC 1988). *Wands* states at page 1404,

> "Factors to be considered in determining whether a disclosure would require undue experimentation have been summarized by the board in Ex parte Forman. They include (1) the quantity of experimentation necessary, (2) the amount of direction or guidance presented, (3) the presence or absence of working examples, (4) the nature of the invention, (5) the state of the prior art, (6) the relative skill of those in the art, (7) the predictability or unpredictability of the art, and (8) the breadth of the claims."

The nature of the invention and breadth of claims

The claims are broadly drawn to a method for detecting colorectal carcinoma in a human patient by extracting blood serum or plasma, measuring an amount of a nucleic acid associated with encoding catenin and determining the possibility of the presence of colorectal cancer based on the amount beta-catenin nucleic acid.

The invention is in a class of invention which the CAFC has characterized as "the unpredictable arts such as chemistry and biology." Mycogen Plant Sci., Inc. v. Monsanto Co., 243 F.3d 1316, 1330 (Fed. Cir. 2001).

The unpredictability of the art and the state of the prior art

Adenomas are benign epithelial tumors arising in epithelium of mucosa (stomach, small intestine and bowel), glands (endocrine and exocrine) and ducts. Thus, Adenomas are not cancer.

The art (Wong et al. Clinical Cancer Research, Vol. 10, pages 1613-1617, March 2004) teaches the quantification of plasma b-catenin mRNA in colorectal cancer and adenoma patients. Wong teaches detecting mRNA in plasma in colorectal carcinoma, colorectal adenoma and normal subjects. The results are listed below.

Carcinoma	1480-933100
Adenoma	541-2254
Normal	0-1366

Wong teaches that b-catenin mRNA was detected in the plasma of all 58 colorectal cancer patients; 49 colorectal adenoma patients and 36 or 43 **(84%)** of normal subjects. Thus, the majority of normal patients express b-catenin mRNA in the plasma. Figure 1A illustrates the overlapping ranges of mRNA copies in plasma. Wong states that a more intensive study is necessary to explore whether plasma b-catenin mRNA concentration may be a prognostic factor. Wong further proposes that a large-scale study would be needed to investigate whether plasma b-catenin mRNA might have a role in population screening for colorectal cancer (page 1616, col. 2).

Osman et al (Clin Cancer, Res. Vol. 12, No. 11, pages 3374-3380, June 2006) teaches analysis of biomarkers in the blood for various cancers. Osman teaches testing a hypothesis that blood cell gene expression can differentiate between different cancers as well as between controls. Osman teaches concludes the gene expression patterns

found in bladder cancer was distinguishable from other cancers. Thus, Osman teaches an expression pattern for one gene in the blood is not indicative of any cancer.

Fleischhacker et al. (Biocheimica et Biophysica Acta, Vol. 1775, pages 181-232, 2007) provides a review of circulating nucleic acids (CNAs) and cancer. Fleischhacker teaches that contradictory results have been publised between the detection of free-circulating plams mRNA and clinical data (page 214, col. 2). Fleischhacker teaches the DNA yield from serum is higher than that from plasma (page 219, col. 1).

Guidance in the Specification.

The specification teaches analysis of plasma RNA in carcinoma, adenomas and normal individuals. The results showed that 100% of patients with carcinoma, 11/14 patients with adenoma and 1/10 healthy volunteers carried b-catenin RNA (page 6, lines 19-25). The specification further teaches a quantitative analysis of plasma blood B-catenin RNA. The specification teaches the adenoma b-catenin mRNA was 30 fold higher than in normal individuals.

Carcinoma	6700-44000
Adenoma	690-1800
Normal	0-169

The specification further teaches detection of b-catenin DNA in serum of patients with colorectal adenoma and carcinoma. The specification teaches that serum B-catenin DNA is detectable in all patients with colorectal carcinoma and 9/10 patients with

colorectal adenoma, while all 10 healthy individuals were free of serum b-catenin DNA (page 9, lines 12-15).

The guidance provided by the specification amounts to an invitation for the skilled artisan to try and follow the disclosed instructions to make and use the claimed invention.

Quantity of Experimentation

The quantity of experimentation in this area is extremely large since there is significant number of parameters which would have to be studied.

The claims are directed to measuring an amount of a nucleic acid encoding catenin, namely beta-catenin nucleic acid. The skilled artisan would be unable to measure an amount of b-catenin as a positive indicator of cancer because the results illustrate overlapping ranges of cancer, adenoma and normal individuals with circulating b-catenin.

The concentration taught in the specification for carcinoma patients ranges from 6700-44000 and the range in normal patients is 0-169. The ratio of 6700/169= 39 which is within the range for adenoma. This again provides results inconsistent with the claims. Therefore, the quantitative ratios provided in the claims to not appear to enable any reliable detection of carcinoma, adenoma or absence of carcinoma/adenoma. The skilled artisan would be unable to use the teachings to accurately determine the status of the patient.

Furthermore, the claims are drawn to serum or plasma levels. Fleischhacker teaches the DNA yield from serum is higher than that from plasma (page 219, col. 1). The instant specification only provides quantitative analysis for plasma. There is no

indication that the serum and plasma levels are in proportion. Therefore, since the art teaches that the serum and plama levels are expected to differ. And there are no teachings how these levels for b-catenin differ, the skilled artisan would be required to perform further experimentation which is unpredictable to determine how the ratios in the different populations range. There is no expectation that the ranges will not be overlapping, as the plama levels are overlapping.

The claims are directed to "a nucleic acid associated with encoding catenin". The response to the restriction requirement asserts that a gene-encoded alpha-catenin; and a gene encoded E-cadherin are associated genes. The instant specification fails to provide any analysis of a gene-encoded alpha-catenin; and a gene encoded E-cadherin and colorectal cancer. As noted above, Osman teaches that each gene has different profiles in different cancers and thus would require analysis to confirm the pattern of the expression. The art similarly fails to provide any analysis. With regard to the quantification claims, there is no analysis of the concentration of the "associated" genes and whether the same ranges are applicable.

This would require significant inventive effort, with each of the many intervening steps, upon effective reduction to practice, not providing any guarantee of success in the succeeding steps.

Level of Skill in the Art

The level of skill in the art is deemed to be high.

Conclusion

In the instant case, as discussed above, in a highly unpredictable art where the art and the specification do not support the claims. Further, the prior art and the

specification provides insufficient guidance to overcome the art recognized difficulties in cancer diagnostics in the serum and plasma. Thus given the broad claims in an art whose nature is identified as unpredictable, the unpredictability of that art, the large quantity of research required to define these unpredictable variables, the lack of guidance provided in the specification, the absence of a working example and the negative teachings in the prior art balanced only against the high skill level in the art, it is the position of the examiner that it would require undue experimentation for one of skill in the art to perform the method of the claim as broadly written.

Response to Arguments

The response traverses the rejection. The response provides a significant discussion related to "common sense to the medical profession." MPEP 716.01(c) makes clear that "The arguments of counsel cannot take the place of evidence in the record. In re Schulze , 346 F.2d 600, 602, 145 USPQ 716, 718 (CCPA 1965). Examples of attorney statements which are not evidence and which must be supported by an appropriate affidavit or declaration include statements regarding unexpected results, commercial success, solution of a long - felt need, inoperability of the prior art, invention before the date of the reference, and allegations that the author(s) of the prior art derived the disclosed subject matter from the applicant." Here, the statements regarding the "common sense to the medical profession" must be supported by evidence, not argument. However, to the extent the arguments are only suggesting a statistically significant association, even less than 100%, that is replicable and robust is required to enable an association, the examiner fully agrees such an association is required.

The response requests that, in order to facilitate the eventual review by the Board, the Examiner is requested to provide the scientific foundation for various positions. For clarity the three remaining issues have been set out and addressed in turn.

Unpredictability of the Claimed Association Given the Teachings of Wong

The response asserts the Wong reference corroborates the present invention. This argument has been reviewed but is not persuasive. The data provided in the chart below illustrates the overlapping ranges such that colorectal cancer can not be detected by measuring the amount of b-catenin. Assuming a skilled artisan analyzed a patients serum and obtained a value of 1,500 B-catenin mRNA copies/ml plasma, the skilled artisan would be unable to effectively determine whether the patient was at risk for colorectal cancer. Using the data provided in the specification, the results would indicate the patient would be in the adenoma range, and no further tests would be performed on the patient since the patient was in the benign range. However, a value of 1,500 copies given the much larger study in Wong would result in a nonconclusive result, as 1,500 is within the range of both carcinoma and adenoma. The skilled artisan would be unable to detect colorectal cancer in the patient as required by the instant claims. Thus, it is unpredictable how the amount of b-catenin determines whether a patient has colorectal carcinoma.

Tables illustrating the data from the specification and Wong (the art) have been provided below to demonstrate the overlapping ranges and unpredictability.

		USSN 10/516,864		Ratio
	N	Range	Median	Range/(36)(median value for normal)
Carcinoma	18	6700-44000	22,000	186-1222
Adenoma	12	690-1800	1,100	20-50
Normal	14	0-169	36	0-5

		Wong		Ratio
	N	Range	Median	Range/(291)(median value for normal)
Carcinoma	58	1,480-933,100	8737	5-3206
Adenoma	49	541-2,254	1218	1.9-7.7
Normal	43	0-1,366	391	0-4.69

This illustrates the overlapping ratios and ranges and provides evidence of the unpredictable results. In another example, in the event that one were to obtain a ratio of 5, looking at applicants data in the specification, the person is deemed normal. However, looking at the data from Wong, a ratio of 5 indicates both adenoma and carcinoma. It is unclear how to determine whether a person is normal or has cancer based upon such a ratio. Looking at the ratio of adenoma, the ratio from Wong is not

within any of the ranges from the specification. Thus, it is unpredictable. Similar discrepancies could be noted with the ranges, medians and ratios.

The response filed June 26, 2008 asserts that one of skill in the art may decide the baseline or threshold to be set at 540, above which the measurement would indicate presence of an abnormal amount of beta-catenin mRNA and need for more invasive check for possible presence of adenoma and carcinoma. This argument has been reviewed but is deemed not persuasive. The specification provides no thresholds or baselines. The specification does not suggest further invasive checks if a particular value is found. The claims are directed to measuring an amount of nucleic acid and determining a possibility of the presence colorectal cancer. The specification does not provide the necessary guidance for the skilled artisan to determine the possibility of the presence of colorectal cancer based upon an amount of beta catenin.

The declaration under 37 CFR 1.132 filed January 15, 2008 is insufficient to overcome the rejection of the claims based upon the unpredictability in the art as set forth in the Office action. The declaration appears to be directed only to part of the enablement rejection to clarify the results and provide a figure illustrating the results in para 30 of the specification. The declaration further provides an explanation regarding the authorship of the Wong references, however, this does not appear to be related to the enablement rejection.

MPEP 2164 states that while a later dated publication cannot supplement an insufficient disclosure in a prior dated application to make it enabling, applicant can offer the testimony of an expert based on the publication as evidence of the level of skill in

the art at the time the application was filed. Gould v. Quigg, 822 F.2d 1074, 1077, 3 USPQ2d 1302, 1304 (Fed. Cir. 1987). If individuals of skill in the art state that a particular invention is not possible years after the filing date, that would be evidence that the disclosed invention was not possible at the time of filing and should be considered. Here the teachings of Wong illustrate the unpredictability of detecting colorectal carcinoma by measuring an amount of beta-catenin. Wong demonstrates the unpredictability in the art related to the levels of B-catenin in plasma and serum as indicative of colorectal cancer. The response asserts that the statement from Wong as using plasma b-catenin RNA measurements for screening for colorectal cancer is just one statement. This argument has been reviewed, but not convincing. Wong clearly teaches the analysis, similar to the instant specification, but cautions the use of the data without additional investigations and a large scale study. It does not appear to be contrary to the entire reference as a whole because Wong while noting a potential of plamsa B-catenin mRNA as a marker for colorectal cancer patients, suggests additional experimentation is needed prior to using this as a diagnostic screening, as specifically claimed in the instant claims. The Wong reference provides data of overlapping ranges, and data which raises the issue of unpredictability of the art and the enablement of the instant claims.

Unpredictability of Correlation Inferring Plasma Results in light of Serum Results

The claims are drawn to serum or plasma levels. The response asserts that the "difference between serum and plasma measurements says nothing, one way or the other, about whether a serum measurement would correlate with a certain disease." The response further states that "when the plasma measurement correlates with a disease, there is a strong presumption that a corresponding serum measurement would also similarly correlate." This argument has been reviewed. MPEP 716.01(c) makes clear that "The arguments of counsel cannot take the place of evidence in the record. In re Schulze , 346 F.2d 600, 602, 145 USPQ 716, 718 (CCPA 1965). Examples of attorney statements which are not evidence and which must be supported by an appropriate affidavit or declaration include statements regarding unexpected results, commercial success, solution of a long - felt need, inoperability of the prior art, invention before the date of the reference, and allegations that the author(s) of the prior art derived the disclosed subject matter from the applicant." Here, the statements regarding the ""strong presumption that a corresponding serum measurement would also similarly correlate" must be supported by evidence, not argument. Turning to the declaration filed January 15, 2008, the declarent failed to make such a bold statement. In fact, the declaration fails to make any statements regarding the differences or similarities between serum and plasma levels.

The objective evidence of record, namely Fleischhacker, suggests differences between serum and plasma levels with no reliable correlation. Fleischhacker teaches the DNA yield from serum is higher than that from plasma (page 219, col. 1). The response appears to agree with this analysis since the response states "plasma will

yield a greater amount of RNA and DNA than serum (see page 12 of the response filed January 15, 2008). The instant specification only provides quantitative analysis for plasma. There is no indication that the serum and plasma levels are in proportion. Therefore, since the art teaches that the serum and plama levels are expected to differ. And there are no teachings how these levels for b-catenin differ, the skilled artisan would be required to perform further experimentation which is unpredictable to determine how the ratios in the different populations range. There is no expectation that the ranges will not be overlapping, as the plama levels are overlapping.

The response asserts that para 30 discusses serum analysis. This argument has been reviewed. Example 5 is directed to serum of patients with colorectal adenoma and carcinoma. The specification however fails to provide any analysis of levels, as required by claims 22. As noted by Fleischhacker, and acknowledged by the response, serum and plasma levels vary. Thus, it is unpredictable the level of the b-catenin in serum without further unpredictable and undue experimentation.

With respect to Fleischhacker, the reference is used to demonstrate the differences in serum and plasma levels, thus demonstrating the unpredictability in levels and ratios between serum and plasma. The level determined for serum would not be analogous to the level of plasma. Thus, the claims specifically requiring levels and ratios are unpredictable.

Unpredictability of Measuring the Amount of Any Nucleic Acid Associated with Encoding Catenin in Light of Teachings of B-catenin

The claims are directed to broad genus of nucleic acids "associated with encoding catenin". The response to the restriction requirement asserts that a gene-encoded alpha-catenin and a gene encoded E-cadherin are associated genes. The instant specification fails to provide any analysis or association of a gene-encoded alpha-catenin and a gene encoded E-cadherin and colorectal cancer. Osman teaches that each gene has different profiles in different cancers and thus would require analysis to confirm the pattern of the expression. The art similarly fails to provide any analysis. With regard to the quantification claims, there is no analysis of the concentration of the "associated" genes and whether the same ranges are applicable.

The declaration under 37 CFR 1.132 filed January 15, 2008 states that beta-catenin is representative of many catenin/cadherins and the expression patterns would be similar. The arguments provided in the declaration are not in the form of evidence. The record lacks any evidence of an association between amounts of a gene-encoded alpha-catenin or a gene encoded E-cadherin and colorectal cancer.

The response asserts that no evidence has been provided to contradict the enablement. This argument has been considered but is not convincing because the teachings of Wong, Fleischhacker each suggest that b-catenin amounts would not determine or detect colorectal cancer. Moreover, it is clear that serum and plasma levels differ and as such, the ratios would be different and unpredictable.

The response, filed June 26, 2008, states that an examiner cannot simply use the teachings of the reference as the basis to reject the claimed invention as unenabled, as if the only cited reference speaks the truth when in conflict with the claimed invention. This argument has been reviewed but is not convincing. The examiner has weighed the evidence in the specification, the state of the art, the unpredictability of the art and the evidence in the art to find that it is unpredictable to detect colorectal cancer based upon an amount of nucleic acid.

Thus for the reasons above and those already of record, the rejection is maintained.

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Conclusion

10. No claims allowable.

11. Applicant's amendment necessitated the new ground(s) of rejection presented in this Office action. Accordingly, **THIS ACTION IS MADE FINAL**. See MPEP § 706.07(a). Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within TWO MONTHS of the mailing date of this final action and the advisory action is not mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of

the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the date of this final action.

12. Any inquiry concerning this communication or earlier communications from the examiner should be directed to examiner Jeanine Goldberg whose telephone number is (571) 272-0743. The examiner can normally be reached Monday-Friday from 7:00 a.m. to 4:00 p.m.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Doug Schultz, can be reached on (571)272-0763.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see http://pair-direct.uspto.gov. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

The Central Fax Number for official correspondence is (571) 273-8300.

/Jeanine Goldberg/
Primary Examiner
August 14, 2009